MAY 2 4 2013

510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the PROFEMUR® RENAISSANCE® Classic Stems.

(a)(1) Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd Arlington, TN 38002 (901) 867-4146
Date:	April 03, 2013
Contact Person:	Yuan Li, PhD *Regulatory Affairs Specialist II*
(a)(2) Proprietary Name of Modified Device:	PROFEMUR® RENAISSANCE® Classic Stems
Common Name:	Femoral Hip Stem
Classification Name and Reference:	888.3353 LZO Hip joint metal/ceramic/polymer, cemented or non-porous, uncemented prosthesis Class II 888.3350 JDI Hip joint metal/polymer semi-constrained cemented prosthesis Class II
Subject Product Code and Panel Code:	Orthopedics/87/JDI/LZO
(a)(3) Predicate Devices:	PROFEMUR® RENAISSANCE® Hip Stem, K051995

(a)(4) Device Description

The purpose of this submission is to add a monolithic femoral neck option to the PROFEMUR® RENAISSANCE® Hip System. The PROFEMUR® RENAISSANCE® Classic Stems are monolithic stems manufactured from a forged titanium alloy (ASTM F620) and designed for use in uncemented total hip arthroplasty. The PROFEMUR® RENAISSANCE® Classic Stems offer both reduced flare stems (7 sizes, 10 – 16), and standard flare stems (9 sizes, 10 – 18) and are coated with titanium plasma spray conforming to ASTM F1580, provided by plasma vendors cleared in K123688. The subject device offers two neck offset options, Standard (neutral) and Extended (varus), which are identical to the predicate stems used with modular necks cleared in K100866 and K091423; as well as two proximal flare options, Standard and Reduced. The stem geometry, neck length, and neck offset are designed to create options identical to those available with the predicate modular device.

The subject devices feature one minor additional change in that they have an impaction slot that is oriented 90 degrees from the impaction feature of the predicate device. This is viewed a minor design change, as the rounded slot is not a worse case compared to the predicate design. This modification to the impaction slot was cleared in K123434 and K123688 with similar devices. In addition, these modifications were evaluated by proximal and distal fatigue testing. These modifications do not affect the intended use or alter the fundamental technology of the device.

Instruments used with the system are identical to ones for the predicate system, except for the stem impactor which was reviewed in K123434 and K123688. The subject devices may also be implanted with instruments for alternative surgical approaches, as cleared in K121221 and K122382. Wright has previously provided validation for the cleaning/sterilization of instruments in previous reviews (K122218).

(a)(5) Indications for Use

The PROFEMUR® RENAISSANCE® Classic Stems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The PROFEMUR® RENAISSANCE® Classic Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.

The indications for use can be also found in the package insert previously cleared in

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K123434 and K123688.

(a)(6) Technological Characteristics of the Device
The indications for use of the PROFEMUR® RENAISSANCE® Classic Stems are identical to those for the predicate device (K051995). The subject devices are made from an identical titanium alloy (ASTM F620) and possess an identical titanium plasma spray coating (ASTM 1580) as the predicate device. The PROFEMUR® RENAISSANCE® Classic Stems are designed to provide identical range of sizes, neck lengths, and neck offsets as those provided by the modular predicate with the exception of featuring a monolithic neck design and a slightly modified impaction slot.

(b)(1) Nonclinical Testing
The PROFEMUR® RENAISSANCE® Classic Stems were evaluated by proximal and distal fatigue tests in accordance with ISO 7206-4, 6, and 8 and satisfied the acceptance criteria of each. Range of motion was evaluated in accordance with ISO 21535 and the subject device satisfied the acceptance criteria. The titanium plasma spray coating is applied according to WMT specification and is identical to that used in the predicate device (K051995).

(b)(2) Clinical Testing
Clinical data was not provided for the subject devices.

(b)(3) Conclusions
The indications for use and fundamental scientific technology of the PROFEMUR® RENAISSANCE® Classic Stems are identical to those of the predicate device. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The safety and effectiveness of the PROFEMUR® RENAISSANCE® Classic Stems is adequately supported by the substantial equivalence information, materials information, and nonclinical testing data provided within this premarket notification.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 24, 2013

Wright Medical Technology, Incorporated
% Dr. Yuan Li
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K130984
Trade/Device Name: PROFEMUR® RENAISSANCE® Classic Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI
Dated: April 25, 2013
Received: April 26, 2013

Dear Dr. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For 

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130984 (pg 1/1)

Device Name: PROFEMUR® RENAISSANCE® Classic Stems

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices